**PATENT APPLICATION**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**
**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

In re application of



Eric A. JOHNSON



Appln. No.: 08/458,019 Group Art Unit: 1651



Filed: June 01, 1995 Examiner: H. Lilling

For: FOR IN VIVO PRODUCTION OF ASTAXANTHIN AN*PHAFFIA RHODOZYMA* YEAST OF ENHANCEDASTAXANTHIN CONTENT

**SUBMISSION OF APPELLANT'S BRIEF ON APPEAL**

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Submitted herewith please find an original and two copies of Appellant's Brief on Appeal. A check for the statutory fee of $150.00 is attached. Authorization is also given to charge or credit any difference or overpayment to Deposit Account No. 19-4880. A duplicate copy of this paper is attached.

Respectfully submitted,

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Date: August 23, 2000

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Eric A. JOHNSON


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For: FOR IN VIVO PRODUCTION OF ASTAXANTHIN AND PHAFFIA RHODOZYMA YEAST OF ENHANCED ASTAXANTHIN CONTENT

**APPELLANTS' BRIEF ON APPEAL UNDER 37 C.F.R. § 1.192**

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In accordance with the provisions of 37 C.F.R. § 1.192, Appellant submits the following:

## I. REAL PARTY IN INTEREST

The Real Party in Interest in this Appeal is Igene Biotechnology, Inc. Assignment of the application was submitted to the U.S. Patent and Trademark Office in application No. 07/399,183.

## II. RELATED APPEALS AND INTERFERENCES

There are no known Appeals or Interferences that will affect, be directly affected by, or have a bearing on the Board's decision in the pending appeal.

## III. STATUS OF CLAIMS

Claims 25-34 remain pending in the application

Claims 25-34 were finally rejected, for example, in a September 23, 1999 Office Action. The present claims were originally numbered 33-42 in the December 16, 1993 Amendment Under 37 C.F.R. § 1.115. The claims were renumbered in accordance with the April 7, 1994 Communication from the Examiner.

The rejection of each of claims 25-34 is appealed.

## IV. STATUS OF AMENDMENTS

All requested Amendments have been entered.

## V. SUMMARY OF THE INVENTION

The invention is directed to an astaxanthin mutant *Phaffia rhodozyma* producing more astaxanthin than naturally occurring *Phaffia rhodozyma*. The mutant of the present invention, as patentably characterized in the single generic claim on appeal, produces more than 700 μg of astaxanthin per gram of dry yeast per 6-day culture in YM medium. The production amount is determined by measuring the absorbance, at 474 nanometers, of a petroleum ether extract of *Phaffia rhodozyma* using a 1% (w/v) extinction coefficient in a one centimeter cuvette of 2100. Claim 25.

Additional embodiments feature mutant yeasts producing more than 900 (claim 26), 1100 (claim 27), 1400 (claim 28), or 1700 μg (claim 29) of astaxanthin per gram of dry yeast.

The invention is also characterized as featuring a mutant yeast producing astaxanthin at a level at least two times (claim 30), three times (claim 31), 4 times (claim 32), five times (claim 33), and six times (claim 34) that of naturally occurring *Phaffia*.

## VI. ISSUES

In the September 23, 1999 Final Office Action, paragraph 3 states "all of the prior rejections as stated in the prior Office Action dated July 29, 1998 and December 2, 1998 have been maintained".

However, in the September 23, 1999 Office Action the Examiner only specifically discusses written description rejections and apparent enablement rejections.

The December 2, 1998 Office Action, at paragraph 19 reproduces the paragraph 19 of the July 29, 1998 Office Action. In paragraph 19, claims 25-34 are rejected under the judicially created doctrine of obviousness-type double patenting over claims of U.S. Patent No. 5,356,810 (Fleno).

Paragraph 20 of the December 2, 1998 Office Action, restates paragraph 20 of the July 29, 1998 Office Action. In paragraph 20, claims 25-34 are rejected under 35 U.S.C. § 112, first

paragraph as allegedly lacking enablement. The lack of enablement rejection at paragraph 20 asserts that a deposit is necessary in order to make and/or use the invention.

The rejection at paragraph 21 (both in the December 2, 1998 and the July 29, 1998 Office Actions) rejects claims 25-34 under 35 U.S.C. § 112, first paragraph, also as allegedly lacking enablement. The Examiner asserts that Applicant does not teach in the instant specification any and all mutant strains to produce pigments at a certain level but only specific mutant strains. September 23, 1999 Office Action, page 7, lines 11-13.

At paragraph 22 in both the December 2, 1998 and the July 29, 1998 rejections, claims 25-34 are rejected under 35 U.S.C. § 112, first paragraph as allegedly lacking adequate written description. Finally, in the December 2, 1998 Office Action, paragraph 4, at page 12, claims 25-34 are rejected under 35 U.S.C. § 102(b/e) as allegedly being anticipated by Fleno U.S. Patent No. 5,712,110. The Examiner alleged an effective filing date of April 15, 1998.

The issues thus are whether the present application provides proper 35 U.S.C. § 112 enablement and written description support for the rejected claims; whether a non-statutory obviousness-type double patenting rejection over Fleno 5,356,810 is proper; and whether Fleno 5,712,110 is properly considered and cited as an anticipatory reference.

## VII. GROUPING OF CLAIMS

For the purposes of this Appeal Brief, the claims are grouped as follows:

| | |
|---|---|
| Group I-claim 25 | Group VI-claim 30 |
| Group II-claim 26 | Group VII-claim 31 |
| Group III-claim 27 | Group VIII-claim 32 |
| Group IV-claim 28 | Group IX-claim 33 |
| Group V-claim 29 | Group X-claim 34 |

The claims of the different groups do not stand or fall together with the claims from separate groups. In the Arguments section specific reference to claims and their 35 U.S.C. §112, first paragraph support provides separate argument for the separate groups.

## VIII. ARGUMENTS

### A. The Specification Provides Enabling Disclosure For Each Of Claims 25-34

The September 23, 1999 Office Action did not specifically mention enablement. At page 2, paragraph 3, the Office Action indicated that all prior rejections of the July 29, 1998 and December 2, 1998 Office Actions had been maintained. At page 2, lines 20 to 22, the September 23, 1999 Office Action states:

> "DEPOSITS ARE REQUIRED FOR THESE MUTANTS due to the unpredictability of the claimed subject matter in accordance with the decisions cited in the previous Office Action."

In the December 2, 1998 Office Action, at paragraph 20, claims 25-34 were rejected under 35 U.S.C. § 112, first paragraph as allegedly lacking enablement. The Examiner asserted that "the additional strains are required to practice the claimed invention". The Office Action further asserts that "[a]s a required element it must be known or readily available to the public or obtainable by a repeatable method set forth in the specification." The Office Action further advises that one means of satisfying an enablement requirement is through deposit of additional strains. December 2, 1998 Office Action page 4, paragraph 5.

In the December 2, 1998 Office Action, at page 5, lines 40-44, the Office Action states:

> The prior arguments are not persuasive for one of ordinary skill in the art to reproduce all of the mutants encompassed by the claimed inventions since the claims are drawn to products and not processes.

The Examiner seems to be requiring that every embodiment within the scope of the claims must be made available to the public without any additional work on the part of the public. This contrasts with decisions by the Federal Circuit. See, for example, *Scripps Clinic and Research Foundation v. Genentech, Inc.*, 18 USPQ2d 1001, (CAFC 1991) and 18 USPQ2d 1896 (CAFC 1991), wherein deposit of a monoclonal antibody was not necessary; *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 18 USPQ2d 1061 (CAFC 1991), wherein the Federal Circuit affirmed a District Court's decision that there was no violation of the best mode requirement by failing to deposit the preferred cell line because the specification adequately taught persons skilled in the art to make equivalent, though not identical, cell lines; and *In re Wands,* 8 USPQ2d

1400 (CAFC 1988), which declined to require deposit of antibody samples that could be obtained by screening following the procedures in the specification.

Thus, it is clear that there is no clear legal burden placed upon Applicants (or Appellants) to restrict their claims to only those embodiments for which they have produced and deposited samples in a depository.

In the present application whose claims are on appeal, the specification identifies the ATCC as a source for wild type *Phaffia*. The ATCC numbers are 24230 and 24202. Page 18, line 24; and page 23, line 12. These wild *Phaffias* are strains that the skilled artisan would have had at his or her disposal for making high astaxanthin producing yeasts of the present invention. Specific examples are described in the specification at pages 23-32.

General guidance to the skilled artisan is also found in the present specification. For example, the specification at page 6, at lines 22-28, describes the basic process for obtaining the high astaxanthin producing *Phaffia* of the present invention as: a) culturing a microorganism of the genus *Phaffia* in a nutrient medium containing an antibiotic, a cytochrome B inhibitor or a terpenoid synthetic pathway inhibitor; b) cultivating surviving pigment enhanced microorganisms; and c) harvesting the yeast. As indicated in the next paragraph of the specification, the key step in strain development is the morphological selection step. Page 6, lines 29 and 30.

Additional specific details to aid the skilled practitioner in practicing the basic process are set forth in the specification. For example, pH, temperature, light intensity, glucose content

and other carbon source to be used during the culturing are discussed in the specification at page 11, second paragraph through page 12, second paragraph. Various manipulations of conditions or selection procedures that were not very successful are described in the specification at page 13, first paragraph though page 14, penultimate paragraph. These teachings are instructive to the skilled artisan for avoiding probably futile experimentation when attempting to make and culture high astaxanthin producing *Phaffia*. Several different protocols for producing the *Phaffia* of the present claims on appeal are described in the specification, for example, at page 15, second paragraph, the morphological selection process using an antibiotic, a cytochrome B inhibitor or a terpenoid synthetic pathway inhibitor is described. At page 16, fourth paragraph, examples of agents that were found to be ineffective for producing the presently claimed *Phaffia* are listed.

Exemplary antibiotics, cytochrome B inhibitors and a terpenoid synthetic pathway inhibitor are named in the specification at page 16, second paragraph. Useful concentrations of these selection agents are found in the specification at page 16, third paragraph.

Optionally using a mutating agent to enhance the selection process is discussed in the specification at page 17, fourth paragraph, through page 18, third paragraph. This discussion includes a list of exemplary and preferred mutagenic agents.

Furthermore, at page 7, lines 3-5, the specification states that "[r]ecent results confirm the reproducibility of this technique". Additional Declaration evidence to be discussed below provides further supportive proof of the stated reproducibility. The Examiner has not explained a cogent reason why the disclosed process of making the claimed *Phaffia* in conjunction with the

disclosure of possible methods that failed to produce the desired results would not have fully enabled the skilled artisan to make the claimed invention.

Specifically, Appellants refer to the Declaration Under 37 C.F.R. §1.132 filed September 23, 1993 wherein the Experiments follow the procedures of the instant specification. First, Appellants respectfully reference page 18 of the specification, last paragraph, wherein from naturally occurring parent 67-385 (obtained from ATCC No. 24230) higher pigmented progeny were obtained following antimycin selection. First strain IGI-887J0 was obtained. When this strain was replated and reselected with antimycin, even higher astaxanthin producing colonies were obtained. Page 19, first paragraph.

The specification at page 19, second paragraph, describes further selection of replated IGI-887J0, this time with nitrosoguanidine, that also resulted in an even higher astaxanthin producing colony, IGI-887J2. At page 19, last paragraph, the strain IGI-2880B60 with an astaxanthin content of 1700 μg/g was obtained by NTG (nitrosoguanidine) mutagenesis from IGI-887J2.

Experiments 1 and 2 of the Declaration Under 37 C.F.R. §1.132 filed September 23, 1993 describe results from the laboratory records of replating strain IGI-887J2 and selecting with nitrosoguanidine as described in the specification at page 19, last paragraph. Additional strains having enhanced astaxanthin content were isolated. The replating used the same medium, YM (yeast malt extract medium), as the Examples 1, 2, 3, 5 and 6 of the specification (pages 23-26).

Experiments 3 and 4 of the Declaration Under 37 C.F.R. §1.132 filed September 23, 1993 show results of further nitrosoguanidine treatment. Sixty-seven strains having enhanced astaxanthin content are reported.

Experiment 5 reports strains obtained following irradiation with UV light. Experiment 6 reports results of selection with tunicamycin. Experiment 7 reports results of selection with mevalonic acid lactone. These are all methods according to the present specification. See, e.g., the specification at page 23, Example 1: Ultraviolet Mutagenesis (Experiment 5); page 24, Example 2: Nitrosoguanidine Mutagenesis (Experiments 1-4); page 25, Example 4: Tunicamycin Treatment (Experiment 6); and page 25, Example 6: Mevalonic Acid Lactone Treatment.

In view of the disclosures in the specification and the additional evidence in the Declarations, Appellants respectfully submit that the specification, especially those parts specifically referenced above, would have been fully enabling to the skilled artisan for making yeasts of the present claims. That is, the present specification teaches a reproducible process for obtaining the enhanced astaxanthin yeasts of the present claims.

Certainly, if there was any doubt as to the reproducibility of the processes described in the specification, Appellants respectfully submit that the 37 C.F.R. §1.132 Declarations evidence (September 23, 1993 and April 1, 1998) provide compelling evidence of enablement. The April 1, 1998 Declaration is a substantial duplicate of the Declaration filed earlier (September 23, 1993, but apparently misplaced in the Office) in the present application.

In the seven Experiments described in the Declarations, 126 strains according to the present invention were produced. Clearly, the disclosed process is reproducible for producing yeast strains according to the present claims.

In summary, Appellants, noting that the specification discloses methods whereby the claimed products can be obtained by a repeatable process (as shown in the specification and in the Declaration under 37 C.F.R. § 1.132 filed April 1, 1998 and/or September 23, 1993), respectfully submit that the enablement requirement is met.

At paragraph 21 of the Office Action, another rejection of claims 25-34 under 35 U.S.C. §112, first paragraph, relating to enablement is discussed.

First, the Office Action cites *In re Fisher*, 168 (166) USPQ 18, 24 (CCPA 1970).

*Fisher* states:

> It is apparent that such an inventor should be allowed to dominate the future patentable inventions of others where those inventions were based in some way on his teachings. Such improvements, while unobvious from his teachings, are still within his contribution, since the improvement was made possible by his work. It is equally apparent, however, that he must not be permitted to achieve this dominance by claims which are insufficiently supported and hence not in compliance with the first paragraph of 35 U.S.C. 112. That paragraph requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art. In cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined,

> other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved. In the present case we must conclude, on the record before us, that appellant has not enabled the preparation of ACTHs having potencies much greater than 2.3, and the claim recitations of potency of "at least 1" render the claims insufficiently supported under the first paragraph of 35 U.S.C. 112. [Emphasis added.]

Appellants respectfully submit that, in accordance with *Fisher,* they can properly dominate future patentable inventions of others where those inventions are based on the present teachings. The present invention features a mutant *Phaffia rhodozyma.* Whether the mutant is produced by random mutagenesis or directed mutagenesis, future patentable or unpatentable inventions that produce 700 μg of astaxanthin per gram of dry yeast per 6-day culture in YM medium with *Phaffia rhodozyma*, or even more potent *Phaffia rhodozyma* strains would clearly be based on the present disclosure. Accordingly, the present claims bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art. Therefore, Appellants respectfully submit that *Fisher* rather than supporting the enablement rejection made by the Examiner, actually supports enablement of the present claims.

In the December 2, 1998 Office Action at the paragraph bridging pages 6 and 7, *Fiers v. Sugano (Revel),* 25 USPQ2d 1601, 1606 (CAFC 1993) is discussed. In *Fiers,* the court required more than a bare reference to a DNA molecule for satisfying the written description requirement:

An adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself. Revel's specification does not do that. Revel's application does not even demonstrate that the disclosed method actually leads to the DNA, and thus that he had possession of the invention, since it only discloses a clone that might be used to obtain mRNA coding for b-IF. A bare reference to a DNA with a statement that it can be obtained by reverse transcription is not a description; it does not indicate that Revel was in possession of the DNA. Revel's argument that correspondence between the language of the count and language in the specification is sufficient to satisfy the written description requirement is unpersuasive when none of that language particularly describes the DNA.

As we stated in *Amgen* and reaffirmed above, such a disclosure just represents a wish, or arguably a plan, for obtaining the DNA. If a conception of a DNA requires a precise definition, such as by structure, formula, chemical name, or physical properties, as we have held, then a description also requires that degree of specificity. To paraphrase the Board, one cannot describe what one has not conceived.

Because the count at issue purports to cover all DNAs that code for b-IF, it is also analogous to a single means claim, which has been held not to comply with the first paragraph of section 112. See *In re Hyatt*, 708 F.2d 712, 218 USPQ 195, 197 (CAFC 1983) ("the enabling disclosure of the specification [must] be commensurate in scope with the claim under consideration.") Claiming all DNA's that achieve a result without defining what means will do so is not in compliance with the description requirement; it is an attempt to preempt the future before it has arrived. [Emphasis added.]

Although the text of *Fiers* specifically relates to satisfying the written description requirement, the Examiner has quoted it as being related to an enablement issue. In *Fiers*, Revel's naked assertion that a DNA molecule was involved did not satisfy the written description requirement. In *Fiers*, the Board concluded that the application in question was not enabling because Revel had not yet conceived the DNA of the count and "[L]ogically one cannot enable an invention that has not been conceived."

Thus, the circumstances of *Fiers* are radically different from the present circumstances. In the present case, the invention has not only been conceived, but reduced to practice. Reference to statements relating to a DNA molecule in *Fiers* that do not apply directly to the present situation dealing with a mutant microorganism should not be sufficient to sustain this rejection.

In the April 1, 1998 Declaration, Appellants have shown that by practicing the methods disclosed in the present application, numerous strains of *Phaffia* in accordance with the present claims are readily produced. The Declaration provides further evidence that the skilled artisan would have (especially after obtaining a deposited sample of wild *Phaffia*) been able to practice the presently claimed invention.

In view of the above, Appellants respectfully urge this Honorable Board to reverse the 35 U.S.C. § 112, first paragraph, enablement rejection of the Examiner.

**B. The Specification Provides Adequate Written Description To Support The Recitations Of Claims 25-34**

The September 24, 1999 rejection of claims 25-34 indicated that all prior rejections of Office Actions dated July 29, 1998 and December 2, 1998 had been maintained. At page 2, line 18, "written description" is specifically mentioned.

Specifically, the Office Action states:

> "This Examiner will probably maintain the above rejections for the broad claimed genus, especially the written description rejections with the approval of the Supervisor and the Special Program Examiner. DEPOSITS ARE REQUIRED FOR THESE MUTANTS due to the unpredictability of the claimed subject matter in accordance with decisions cited in the previous Office Action."

In the previous Office Action (December 2, 1998), at paragraph 22, claims 25-34 were rejected under 35 U.S.C. § 112 first paragraph, as allegedly "containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention."

The Examiner asserts that the description must clearly allow the skilled artisan to recognize what is claimed (at page 8, lines 14 and 15).

The present written description rejection was made prior to publication of **Revised Interim Guidelines for Examination of Patent Applications Under 35 U.S.C. § 112,**

**paragraph 1 "Written Description", Federal Register, Volume 64, no. 244, December 21, 1999**. The Revised Interim Guidelines are based on the Office's current understanding of the law and the public comments received in response to the PTO's previous request for public comments on its Interim Written Description Guidelines. The revision is believed to be fully consistent with binding precedent of the U.S. Supreme Court, as well as the U.S. Court of Appeals for the Federal Circuit and its predecessor courts. Guidelines, page 71434.

Appellants respectfully submit that the written description rejection currently in this application should be reconsidered and withdrawn in accordance with the revised interim guidelines.

Under the current guidelines, with original claims there is a strong presumption that an adequate written description of the claimed invention is present when the application is filed. However, with new or amended claims, the written description requirement prevents an applicant from claiming subject matter that was not adequately described in the specification as filed. "New or amended claims which introduce elements or limitations which are not supported by the as-filed disclosure violate the written description requirement. While there is no *in haec verba* requirement, newly added claim limitations must be supported in the specification by express, implicit, or inherent disclosure." Guidelines, page 71434.

Appellants wish to make clear that the Examiner has not alleged that the specification does not support the present claims. Also the Examiner has not alleged that the present claims are not entitled to priority under 35 U.S.C. §120 to the filing date of the August 8, 1988 parent

application. However, to guide this Honorable Board, Appellants make specific reference to specific claim recitations and cite support therefor in the present specification as well as the August 8, 1988 parent application.

Support for astaxanthin mutant *Phaffia rhodozyma* that produce more astaxanthin than naturally occurring *Phaffia rhodozyma* can be found at many locations in both the present application and the August 8, 1988 parent specification. The references for support are accurate for both applications, for example, at page 18, last paragraph. This paragraph found in both applications also contains an example of a mutant producing more than 700 $\mu$g of astaxanthin per gram of dry yeast for a 6-day culture as recited in claim 25. The measurement protocol recited in claim 25 is supported in the specification, for example, at the paragraph bridging pages 26 and 27. Specific support for the claim 26 recitation of a mutant yeast producing more than 900 μg of astaxanthin per gram of dry yeast can be found in the specification, for example, at page 19, lines 26 and 27. The claim 27 recitation of more than 1100 μg is supported in the specification, for example, at page 19, lines 3 and 12.

Support for the claim 28 recitation of more than 1400 μg can be found in the specification, for example, at page 19, lines 3 and 27.

Support for the claim 29 recitation of 1700 μg can be found in the specification, for example, at page 19, line 32.

The recitations of claims 30-34, at least 2, 3, 4, 5 or 6 times naturally occurring astaxanthin production than naturally occurring *Phaffia*, have specific support in the specification, for example, at page 18, lines 29 through 31 and at page 15, lines 20-24.

Appellants have therefore complied with the suggestion in the revised guidelines that they should show support in the specifications (both in the present specification and the original specification cited for priority) for the new claims (claims that were not in the originally filed application).

Under the revised guidelines, the Examiner is to determine what each claim as a whole covers; that is, the Examiner should evaluate each claim to determine what structures, acts, or functions are recited to make clear the scope and meaning of the claim. Guidelines, page 71435. Appellants respectfully submit that sufficient structure, *Phaffia rhodozyma* with capabilities for producing the recited amounts of astaxanthin, provide the details necessary to make clear the scope and meaning of each claim.

The guidelines also instruct the Examiner to review the entire application for essential features of the invention. The Examiner is instructed to determine the correspondence between what the applicant has described as the essential identifying characteristic features of the invention and what applicant has claimed. Appellants respectfully submit that the claims themselves recite the essential identifying characteristic features of levels of enhanced astaxanthin production.

The next step according to the guidelines, is to determine whether there is sufficient written description to inform a skilled artisan that the Applicant (or Appellant) was in possession of the claimed invention as a whole at the time the application was filed. At page 71436, (part 3b), the Guidelines suggest that when filing an amendment, an Applicant should show support in the original disclosure for new or amended claims. Appellants have indicated above such support in the present application and in the original specification cited for priority.

Thus, each claim limitation is expressly, implicitly, or inherently supported in the present disclosure. Furthermore, each claim includes all elements that have been described as essential. Accordingly, Appellants respectfully submit that under the revised Guidelines, a written description rejection of the present claims is improper.

As additional evidence Appellants refer to the Second Declaration of Stephen Hiu Under 37 C.F.R. §1.132 wherein specific evidence that would have indicated to the skilled artisan that the inventors had possession of the presently claimed invention is discussed. Principally, as stated in the Second Declaration: "The specification conveys with clarity, that as of the filing of the earliest parental application, 8 August 1988, the inventors had indeed made and used *Phaffia* with enhanced astaxanthin content."

The Second Declaration cites as evidence, the numerous examples of yeast with enhanced astaxanthin content provided in the specification. While not questioning the disclosure of the numerous examples in the specification, Dr. Hiu cites as further supportive evidence, the numerous additional Experiments cited in the September 23, 1993 Declaration as further

evidence that the inventors had possession of, i.e., actually reduced to practice, the presently claimed invention.

Furthermore the Federal Circuit in March 2000 has provides additional guidance on what sort of description can satisfy the 35 U.S.C. §112, first paragraph, Written Description requirement.

In *Union Oil Co. of California v. Atlantic Richfield Co.* (CAFC) 54 USPQ2d 1227, 1228 (CAFC 3/29/2000), the Federal Circuit states:

> As illustrated above, the claims do not describe each gasoline product in terms of molecular structures or lists of ingredients. **Instead, the claims specify the chemical properties of the gasolines, reflecting the way oil refiners formulate gasoline.** When oil refiners formulate new gasoline products, they do so by mixing petroleum stocks. Different stocks have different properties that are known to oil refiners. The record shows that oil refiners of ordinary skill in the art change the chemical properties of gasoline by varying the proportions of different petroleum stocks. **Thus the claims which define the invention in terms of various characteristics also inform those of skill in the art of the composition of the claimed gasoline fuels.**

[Emphasis added.]

The Federal Circuit thus instructs that, under present law, reciting defining characteristics of a claimed invention can be sufficient and that disclosure of a molecular structure is not a requirement for satisfying the Written Description requirement. In *Fiers v. Sugano (Revel),* 25 USPQ2d 1601, 1606 (CAFC 1993), discussed above in relation to the 35 U.S.C. §112, first

paragraph, enablement rejection, ("A bare reference to a DNA with a statement that it can be obtained by reverse transcription is not a description; it does not indicate that Revel was in possession of the DNA.") the DNA was not well characterized and there was no evidence that the Revel had obtained the DNA. The present case distinguishes over *Fiers* because more that a bare reference to the claimed invention is made and Applicants provide substantial evidence that the claimed invention was actually in their possession.

Clearly, in the present case where actual reduction to practice has been shown, the skilled artisan would clearly have seen that at the time the application was filed, Applicants had possession of the claimed invention.

Accordingly, Appellants respectfully request that this Honorable Board reconsider and reverse the Examiner's "written description" rejection of the present claims.

### C. The Rejection Over Fleno 5,712,110 Under 35 U.S.C. § 102(b/e) Is Improper

Appellants next address the rejection of claims 25-34 under 35 U.S.C. § 102(b/e) as set forth at page 12, paragraph 4, of the December 2, 1998 rejection.

The September 23, 1999 Office Action, at page 12, numbered paragraph 4, rejects all pending claims under 35 U.S.C. §102(b/e) over Fleno U.S.P. 5,712,110.

The Examiner asserts an effective filing date of April 15, 1988 for Fleno 5,712,110. The Examiner simply states:

The prior art clearly anticipates the broad claimed inventions.

Appellants urge this honorable Board to reverse the Examiner's rejection on any or all of the following grounds.

First Appellants respectfully submit that a rejection under 35 U.S.C. §102(b) is not supported by the Examiner's allegations. In the June 21, 2000 Examiner Interview, The 35 U.S.C. §102(b) rejection was discussed. Examiner Lilling agreed that a rejection under 35 U.S.C. §102(b) appeared to be improper because, no effective date of Fleno indicated publication more than one year prior to the date of application for patent (August 8, 1988). Thus at least the rejection under 35 U.S.C. §102(b) should be withdrawn.

Second, 35 U.S.C. §102(e) is concerned not with Applicants' or Appellants filing date, but with the date of invention. As discussed below, under 35 U.S.C. §102(e) the filing date of a patent is the date that the patent is available as a reference against another application. However, since 35 U.S.C. §102(e) refers to the time of the invention, not the filing date of an application claiming the invention, a simple comparison of filing dates is not dispositive for a rejection under 35 U.S.C. §102(e). A 35 U.S.C. §102(e) rejection can be overcome by demonstrating an invention date before the "effective filing date" of the applied reference.

On April 2, 1999, Appellants filed a Declaration Under 37 C.F.R. § 1.131 asserting an invention date prior to April 15, 1988, the date alleged as the effective filing date in the December 2, 1998 Office Action. Appellants do not agree that the effective filing date alleged by the Examiner is in fact the proper 35 U.S.C. §102(e) date. This April 15, 1988 filing date is

the date that the international PCT application upon which the Fleno U.S. application relied was filed.

35 U.S.C. §102(e) does not recognize an international filing date as a basis for a 35 U.S.C. §102(e) date. The 35 U.S.C. §102(e) is the date that the U.S. application was filed or the national stage entry was satisfactorily completed. Nevertheless, even taking April 15, 1988 as a 35 U.S.C. §102(e) date Appellants have properly obviated this rejection of the Examiner.

In the September 23, 1999 Office Action, the Examiner failed to comment on the Declaration. However, the Examiner also did not specifically refer to this rejection. It is not clear whether the Examiner's general statement that all prior rejections had been maintained was meant to apply to the rejection under 35 U.S.C. § 102. If the Examiner intended to maintain the rejection, the Examiner should have provided an explanation why the Declaration Under 37 C.F.R. § 1.131 was not effective for antedating the Fleno patent reference. In the absence of the Examiner's comments on the declaration, Appellants respectfully submit that the Declaration Under 37 C.F.R. § 1.131 filed April 2, 1999 is effective to remove Fleno 5,712,110 as a reference.

However, as briefly discussed above, Appellants respectfully submit that the Fleno 5,712,110 35 U.S.C. §102 rejection of record is improper under the statute. In the June 21, 2000 interview, the Examiner indicated that he would consider (with the advice of others in the Office) Appellants' argument that the International filing date was not the effective date of a patent for purposes of 35 U.S.C. §102(e)

The applicable statute, 35 U.S.C. § 102(e) states:

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The Examiner asserted an effective filing date for Fleno of April 15, 1988. The text of Fleno indicates that it is a continuation of applications back to Serial No. 07/424,306, filed December 11, 1989. December 11, 1989 is the first U.S. filing, not April 15, 1988. Fleno 5,712,110 also refers to a PCT application filed April 15, 1988.

In the past, some practitioners would recommend filing a continuation application of a PCT application under 35 U.S.C. §111 rather than a national stage application of a PCT application under 35 U.S.C. § 371 in the mistaken belief that the §111 application would be granted as a 35 U.S.C. §102(e) date, the date of the filing of the PCT application. There is no indication in the record that the Fleno application 07/424,306 was filed as a continuation under 35 U.S.C. §111, rather than the routine national stage entry under 35 U.S.C. §371. However, in either case as shown below, the Fleno application according to the present law does not have as an effective filing date (for 35 U.S.C. §102(e) purposes), the date of the PCT application filing.

The MPEP, Seventh Edition, Revision 1, February, 2000, at §1896 unambiguously states that the effective filing date of a U.S. application based on a PCT application is not the PCT

filing date. The MPEP paragraph: **EFFECTIVE DATE AS A REFERENCE** (page 1800-125, column 2) states:

> When a U.S. national application filed under 35 U.S.C. 111(a) becomes a U.S. patent, its effective filing date as a prior art reference against a pending application is its effective U.S. filing date other than an international filing date. See 35 U.S.C. §102(e). Thus, if the 35 U.S.C. 111(a) application claims benefit of a prior copending PCT international application under 35 U.S.C. 120, its effective date as a reference will be the U.S. filing date of the 35 U.S.C. 111(a) application and not the international filing date.

Accordingly, the Fleno 5,712,110 35 U.S.C. §102(e) date is apparently December 11, 1989, the filing date listed on the patent cover page, not the April 15, 1988 filing date asserted by the Examiner. Thus the Declaration Under 37 C.F.R. §1.131, while effective for removing the Fleno patent as a 35 U.S.C. §102(e) reference, is dispositive, but not required.

Accordingly, whether Appellants' date of invention is considered to be August 8, 1988 (in accordance with the claim for priority under 35 U.S.C. § 120) or to be prior to April 15, 1988 (as sworn to in the Declaration Under 37 C.F.R. § 1.131), the applied reference is not properly considered as prior art. Appellants respectfully request reversal of the Examiner's rejection under 35 U.S.C. §102 of claims 25-34 over Fleno.

Furthermore, Appellants respectfully assert that Fleno 5,712,110 clearly cannot be said to anticipate claims 26-29 and claims 31-34 that recite yeasts with astaxanthin content higher than any disclosed or claimed in Fleno 5,712,110. For this additional reason Appellants respectfully urge this honorable Board to overturn the 35 U.S.C. §102 rejection over Fleno 5,712,110.

### D. An Obviousness-Type Double Patenting Rejection Of The Present Application Over U.S. Patent No. 5,356,810 Is Improper

Claims 25-34 are rejected under the judicially created doctrine of obviousness-type double patenting. This doctrine is grounded in public policy so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. The text of the December 2, 1998 Office Action indicates that a terminal disclaimer may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with the application.

In the present circumstance a terminal disclaimer is not possible because the inventions are not commonly owned. The Examiner relies upon Table II-B at Section 804 of the MPEP as support for maintaining the obviousness-type double patenting rejection. The Examiner cites this Table while wishing Appellants "the best in the pursuit of overturning the rejections by a higher Authority". September 23, 1999 Office Action, page 2, lines 9-11.

The situation under Table II-B that the Examiner is following is for different inventions that are not patentably distinct. In the case where there is at least one common inventor, but no common assignee, the Table suggests an obviousness-type double patenting rejection, a rejection under 102(e)/103(a) and a rejection under 102(f)/102(a) or 102(g)/103(a).

On April 7, 1994, a communication from the Examiner indicated that *ex parte* prosecution of the application would be suspended for a period of 6 months because a reference relevant to the examination of the application might soon become available. In the February 1,

1995 Office Action, the Fleno reference (USP 5,356,810) was identified as being within the scope of broad claim 25. In a terse rejection, the Office Action only stated "thus, this Examiner cannot allow the instant claims based on the current record." In the October 18, 1995 Office Action, the same Fleno reference was used as a basis to reject claims 25-34 under 35 U.S.C. § 102(b) with the allegation that Fleno was "considered to be within the scope of the broad claims."

In the May 29, 1996 Office Action, the 35 U.S.C. § 102(b)/103 was withdrawn. In its place a rejection under the judicially created doctrine of obviousness-double patenting was instituted. Then in the December 1, 1997 Office Action, Fleno 5,356,810 was again applied, this time under 35 U.S.C. § 102(e) or in the alternative under 35 U.S.C. § 103(a) in rejecting the claims. The April 10, 1998 Office Action, at paragraph 21, maintained a 35 U.S.C. § 102(e)/103(a) rejection without further explanation.

Then in the July 29, 1998 Office Action, the rejection over prior art was withdrawn noting that its effective date was not the priority date but rather the PCT publication date of October 20, 1989. However, in the December 2, 1998 Office Action, the rejection over Fleno under 35 U.S.C. § 102(b)/(e) is reinstituted. This time a different member of the family, USP 5,712,110, is applied. In this Office Action, Fleno is asserted to have an effective filing date of April 15, 1988.

The propriety of statutory rejections over Fleno is discussed above. They are mentioned here as being exemplary of the delays Appellants have faced in obtaining issuance of a patent.

Because of the delays faced by Appellants, the Fleno patent which was filed subsequent to the effective filing date of the present application, issued first as a patent. Thus, Appellants respectfully submit that in accordance with the MPEP, at § 804(II)(B)(1)(b), a two-way obviousness analysis would be proper.

For an obviousness-type Double Patenting Rejection to be made, the MPEP, at § 804(II)(B)(1) instructs that guidelines for a 35 U.S.C. § 103(a) rejection should be followed. For a two-way obviousness determination that Appellants assert is appropriate here, the obviousness analysis must be applied twice. Appellants respectfully submit that the sole claim of Fleno 5,356,810 cannot properly be said to render to the present claims obvious.

Fleno claim 1:

> 1. An isolated pure culture of a strain of *Phaffia rhodozyma* which when grown under conditions comprising an oxygen transfer rate of at least 30 mmoles/1/hour on YM medium at 20.degree.-22.degree. C. for 5 days in 500 ml shake flasks with two baffles containing 50 ml of the medium and subjected to orbital shaking at 150 rpm, produces astaxanthin in an amount of at least 600 μg per g *Phaffia rhodozyma* dry matter, as determined by HPLC analysis, wherein said strain is *Phaffia rhodozyma* deposited under accession No. 224-87 CBS, accession No. 225-87 CBS, or accession No. 215-88 CBS, or a mutant thereof which retains the astaxanthin-producing capability.

The amount of astaxanthin production of the strains claimed by Fleno 5,356,810 (600 μg) cannot properly be said to render the strains of the present claims, each reciting mutant strains producing at least 700 μg of astaxanthin, obvious. Indeed, the Examiner has not applied any

reference, to supplement the Fleno 5,356,810 reference, even suggesting ability in the art for increasing pigment production to that amount achieved by Appellants. The claimed distinguishing features are even more noteworthy concerning the higher production amounts recited in present appealed claims 26-30 and 32-34. Thus, the two-way obviousness determination fails to support an obviousness-type Double Patenting Rejection. Accordingly, Appellants respectfully request this Honorable Board to reverse the Examiner's obviousness-type Double Patenting Rejection.

It is also apparent from the above discussion that even a one-way obviousness analysis fails, i.e., Fleno 5,356,810 in teaching at least 600 $\mu$g astaxanthin per g *Phaffia* does not render 700 $\mu$g or more obvious. The specific growth conditions specifically recited in Fleno claim one cannot be said to be taught or suggested by the present appealed claims. Thus even when a one-way analysis is applied, withdrawal of this rejection is deemed to be proper.

Additionally, Appellants further argue, as they have previously argued that the public policy concerns that serve as the basis for the obviousness-type double patenting rejections do not apply in the present circumstances. Appellants would not be recipients of an unjustified or improper timewise extension of the right to exclude (*In re Goodman*, 29 USPQ2d 2010 (CAFC 1993)). Rather, in the present circumstances, a different owner, has been granted a right to exclude and also has been granted, by the Examiner's application of its patent application in a manner inconsistent with the statutes, an ability to prevent issuance of a patent to the Appellants. Appellants have no opportunity, as occurs in most obviousness-type Double Patenting Rejections

to file a terminal disclaimer. Thus, because Appellants' application did not issue first, according to the Examiner, they should not obtain the fruits of their invention, an entirely inequitable result.

In a recent Federal Circuit Decision, obviousness-type double patenting was considered. In *Lilly v. Barr*, 99-1262, -1263, -1264, -1303 (CAFC 8/7/00), the Court appeared to apply a novel approach to analysis of obviousness-type double patenting.

While citing previous cases, such as *Georgia-Pacific Corp. v. United States Gypsum,* 52 USPQ2d 1590, 1593 and 1595 (CAFC 1999) and *General Foods Corp. v. Studiengesellschaft Kohle,* 23 USPQ2d 1839, 1844, the analysis of obviousness-type double patenting departed from the process as detailed in the MPEP. For example, the MPEP at §804 indicates that the determination for obviousness-type double patenting parallels the guidelines for a 35 U.S.C. §103(a) rejection.

Instead, in *Lilly*, a two step analysis was used: First, the claims are analyzed. Second, the court determines whether the difference between the subject matter of the two claims is such that the claims are patentably distinct.

After setting forth this method of analysis, the Court modified this stated method and instead determined whether the earlier claim covered subject matter claimed in the latter. No consideration of patentably distinguishing features (non-obviousness) appeared to be relevant with respect to the actual recited compounds.

The Court's *Lilly* analysis concluded that the fluoxetine hydrochloride recited in the latter claim was encompassed as one of the compounds of the earlier claim. In other words since the

compound in the latter claim was a species of an earlier recited genus, the earlier claim covered the later claimed administration of fluoxetine hydrochloride for treatment of depression.

The Court did acknowledge that in several cases, species claims were not necessarily obvious in light of a prior art disclosure of a genus. **However, the Court distinguished the cited cases with an observation that in *Lilly* the same party was claiming a species of an earlier claimed genus.**

In the present rejection, two different parties are involved. The party with the second filed application has a patent that is being used against an earlier filed application. The public policy reasons behind the obviousness-type double patenting rejection would militate against this outcome.

In the *Lilly* decision, the analysis as outlined in the MPEP, i.e., applying the *Graham* analysis is ignored by the Court. Thus, the procedures outlined in the MPEP, for example, the Double-Patenting Chart relied upon by the Examiner, are not to be automatically applied.

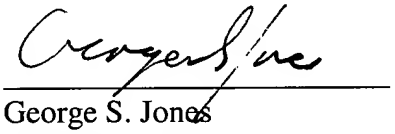
For at least this additional reason, Appellants beseech the Board to accede to the Examiner's best wishes for Appellants in their pursuit of overturning the obvious-type Double Patenting Rejection that the Examiner felt he was compelled to make by the MPEP § 804 at II-B. Reversal of the Examiner in this rejection is respectfully urged.

## IX. CONCLUSION

Appellants respectfully assert that all pending rejections are improper and request that the Examiner's rejections under 35 U.S.C. § 102(b)/(e)/103; 35 U.S.C. § 112, first paragraph; and based on obviousness-type double patenting of claims 25-34 be reversed.

The present Brief on Appeal is being filed in triplicate. Appellant hereby petitions for any extension of time which may be required to maintain the pendency of this case, and any required fee for such extension is to be charged to Deposit Account No. 19-4880.

Respectfully submitted,



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# APPENDIX

25. An astaxanthin mutant Phaffia rhodozyma producing more astaxanthin than naturally occurring Phaffia rhodozyma, said mutant producing more than 700 micrograms of astaxanthin per gram of dry yeast per six-day culture in YM medium, wherein the amount of astaxanthin is determined by measuring the absorbance at 474 nanometers of a petroleum ether extract of Phaffia rhodozyma using a 1% (w/v) extinction coefficient in a one centimeter cuvette of 2100.

26. The mutant yeast of claim 25, wherein said mutant yeast produces more than 900 μg of astaxanthin per gram of dry yeast.

27. The mutant yeast of claim 26, wherein said mutant yeast produces more than 1100 μg of astaxanthin per gram of dry yeast.

28. The mutant yeast of claim 27, wherein said mutant yeast produces more than 1400 μg of astaxanthin per gram of dry yeast.

29. The mutant yeast of claim 28, wherein said mutant yeast produces more than 1700 μg of astaxanthin per gram of dry yeast.

30. The mutant yeast of claim 25, wherein said mutant yeast produces astaxanthin at a level at least two times that of naturally occurring Phaffia rhodozyma.

31. The mutant yeast of claim 30, wherein said mutant yeast produces astaxanthin at a level at least three times that of naturally occurring Phaffia rhodozyma.

32. The mutant yeast of claim 31, wherein said mutant yeast produces astaxanthin at a level at least four times that of naturally occurring Phaffia rhodozyma.

33. The mutant yeast of claim 32, wherein said mutant yeast produces astaxanthin at a level at least five times that of naturally occurring Phaffia rhodozyma.

34. The mutant yeast of claim 33, wherein said mutant yeast produces astaxanthin at a level at least six times that of naturally occurring Phaffia rhodozyma.